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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,839	12/21/2001	Richard Derose	022650-685	4793

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,839	DEROSE ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 Aug 2005 + 09 Feb 2006 interview*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *2-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

9 Feb 2006

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Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. ~~Feb2006~~.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Supplemental Action

1. In response to the personal interview of 09 February 2006, in which Applicant's representative objected to the outstanding restriction requirement which was erroneously based upon lack of unity practice under 37 USC 372, the Office Action mailed 12 October 2005 is hereby VACATED in favor of the following supplemental Office Action.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 August 2005 has been entered.

Status of the Claims

3. Claim 1 and new claims 2-12 are pending. New claims 2-12 are subject to restriction, as indicated below.

4. All rejections not addressed below have been withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

6. Newly submitted claims 2-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an isolated intron of the non-translated 5' region of a plant H3.3 gene, classified in class 536, subclass 24.1, for example.

II. Claims 2-12, drawn to methods of making a chimeric gene comprising ligating an intron, promoter, and coding sequence conferring herbicide resistance; the resultant chimeric gene; methods for plant transformation therewith; and the resultant transformed plants; classified in class 800, subclass 300, for example.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as probing other plant genomes to assay for the presence of introns in native genes.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different

effects. Invention I involves isolated introns not required by Invention II. Invention II involves heterologous coding sequences including herbicide resistance-conferring sequences, heterologous promoters, methods of plant transformation and regeneration, and living plants, each not required by Invention I.

It is also noted that newly presented claims 2-12, presented with the Request for Continuing Examination of 22 August 2005, correspond to original claims 9-24 filed with the application, which were voluntarily cancelled by the preliminary amendment of 21 December 2001. The subject matter of original claims 9-24; namely chimeric genes comprising introns, plant promoters and herbicide resistance genes (original claims 9-19), vectors comprising them (original claim 20), plant cells and plants transformed therewith (original claims 22-23), and methods of making the chimeric gene (original claim 24); was never examined during the original prosecution of the instant application.

See also MPEP 706.07(h), where it is stated that "applicant cannot switch inventions" upon filing an RCE, and where it is stated that "any newly submitted claims that are directed to an invention that is independent and distinct from the invention previously claimed will be withdrawn from consideration." See also 37 CFR 1.145.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Group I claim (claim 1) is examined in the instant action and Group II claims (2-12) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112-written description

7. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Actions mailed 2 July 2004 and 18 April 2005.

Applicant traverses saying primarily (Response, p. 5) that the only basis on which the Examiner is maintaining the rejection is that Applicant has not "defined the size or size range of the 5' region in which the expected 5' intron would occur". Applicant asserts that "while the size of introns may be variable, the expected range of plant intron size would have been known to a person of ordinary skill in the art and therefore it is not necessary for such to be described herein", citing Sinibaldi, op. cit. Applicant further asserts that "one skilled in the art would have recognized the bounds of any particular plant intron by the conserved splice junction sequence which define the bounds of every

plant intron", again citing Sinibaldi, at Tables I and II (Response, ¶ bridging p. 5 and p.6).

Applicant's traversal is unpersuasive. Sinibaldi's discussion of Tables I and II (p. 233-234), titled " nucleotide frequencies . at the 5' [and at the 3'] splice junctions of monocot and dicot introns", states that the "great variability within the proposed consensus sequence of the 5' splice site has prompted some to subclassify the "eukaryotic" intron consensus into separate motifs, ...in an attempt to define patterns necessary and sufficient for recognition of the 5' splice site. Although most moncot and dicot introns can be separated into such categories, enough variability remains to question the usefulness of such a process." See ¶ bridging pages 235-236. Quoting Sinibaldi "there is much variability among different introns, even within the same gene. Examples of authentic introns that appear to conflict with the general consensus rules..can be found". (Page 238, bottom ¶).

Applicant's traversal is unpersuasive. Applicant states that all introns have consensus sequences in the 5' and 3' splice sites and these are known to the skilled person as evidenced by Sinibaldi, 1992. Whereas Applicant has exemplified two H3.3 histones from Arabidopsis in the instant case, Applicant had additional information relating to the Arabidopsis genes—information which was required for this exemplification. This information includes: a single large intron was known to be located in the 5' non-translated region of each of the Arabidopsis genes (Chaubet et. al. 1992); Applicant also had information about the size of the 5' non-translated region (Chaubet et. al. 1992, p.572).

Applicant cites a recent case, *Capon v. Eshhar v. Dudas*, No. 03-1480 (Fed Cir 2005), saying that "there is no per se rule that sequences of claimed DNA molecules must be given ...in order to fulfill the written description requirement", and that the written description requirement must be applied in the context of the particular invention and the state of the art (Response, p. 7). Applicant maintains that Chaubet teaches that corresponding genes exist in other plants, and that the structural features common to plant introns are well understood so that the recited introns could be recognized.

Applicant's traversal is unpersuasive. Applicant has not defined a size or size range of the 5' region in which the expected 5' intron would occur. Sinibaldi, 1992, teaches that introns range in size from 36 bp to greater than 100,000 bp (p. 230). Therefore, thousands of kbs of DNA are 5' to the claimed sequence. Nor has Applicant defined a size range of the expected intron. Applicant has provided these descriptions for the two Arabidopsis H3.3 genes exemplified. Applicant's claims, however, are drawn to a DNA sequence which is the intron of the 5' non translated region of a plant H3.3 histone gene, wherein the plant is unspecified and includes the taxonomically divergent species duckweed, palm, orchid, iris, soybean, rice, Eucalyptus and sequoia trees.

See also Sinibaldi, 1992, paragraph bridging pages 237 and 238, where it is taught that the introns of monocots and dicots differ with regard to A-T content and splicing efficiency. Thus, Applicant's two species, namely the introns from the H3.3 genes of a single genomic clone of the single dicot plant species *Arabidopsis thaliana*

(see, e.g., page 26 of the specification, lines 12-18; page 27, lines 3-7 and 15-16), is not representative of the broadly claimed genus, encompassing introns of H3.3 genes from any plant species including both monocots and dicots.

Regarding *Capon*, the Examiner maintains that different fact patterns are involved in the instant application. In *Capon*, the claims encompassed the well-developed antibody art, wherein "over 785 mouse antibody DNA light chains and 1,327 mouse antibody DNA heavy chains were known and published as early as 1991" (see page 10 of *Capon* decision appended to the amendment of 22 August 2005, middle paragraph). In the instant application, Applicant isolated two 5' introns from the H3.3 gene of a single genomic clone of a single plant species, and no H3.3 5' introns from any other genes or plant species were reduced to practice or otherwise known in the art.

Claim Rejections - 35 USC § 112-enablement

8. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record set forth in the Office Actions mailed 2 July 2004 and 18 April 2005.

Applicant traverses that the one "of ordinary skill in the art could identify and obtain any 5' intron of a plant H3.3 gene using routine methods...and as further evidenced by the exemplary sequence alignments provided" (Response, p. 8) in Attachment A. Applicant further asserts "it should be noted that under similar circumstances in Capon, supra, the BPAI presumed and the Federal Circuit did not overturn this presumption (Response, p. 9) .

Applicant's traversal is unpersuasive. Applicant provides (Exhibit A) a BLAST search which "show that the histone H3.3 from rice and vine share 100% identity with the one of Arabidopsis from which the intron disclosed in the Examples have been isolated." (Response of 2 November 2004, p. 9, top ¶).

It is noted that Applicant's BLAST searches depict amino acid sequences from histone proteins, rather than nucleic acid sequences from introns of 5' untranslated gene regions. As taught by Sinibaldi discussed above, intron regions may differ significantly among different plant species, particularly between monocots (such as rice) and dicots (such as grapevine).

Applicant's disclosure has provided information on the 5' regions of two H3.3 histone genes of Arabidopsis, a dicot angiosperm plant. The sequence information for the two examples given, rice and vine, necessary for this determination was available as of February 2004 and May 2003 respectively (see NCBI accessions AAS19511 and AAP307390). The specification must be complete as of the date of filing, whereas the cited information was not available as of the date of earliest filing date of the instant case (19 July 1995).

See In re Glass, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Furthermore, the introns of Applicant's exemplified SEQ ID NO: 6 and 7 are relatively small, about 400 bp, and are very AT-rich DNA, ca. 71% (Sinibaldi Table IV, p.

238) which means that heterologous probes will not hybridize stringently compared to GC-rich regions.

Given the sequence divergence of introns as taught by Sinibaldi discussed above, undue experimentation would have been required by one skilled in the art to attempt to isolate a multitude of introns from a multitude of non-exemplified plant species as broadly claimed. Furthermore, given the different behavior of introns in monocots versus dicots, undue experimentation would have been required to evaluate the ability of any isolated putative introns to actually function as such in heterologous plant host species.

Remarks

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
8 March 2006

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